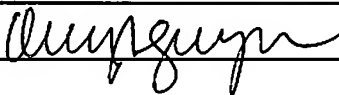
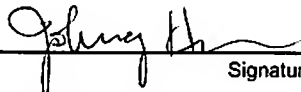


Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) USGINZ02112							
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>August 16, 2010 (VIA EFS)</u></p> <p>Signature <u></u></p> <p>Typed or printed name <u>Quyen Nguyen (VIA EFS)</u></p>		<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;">Application Number 10/612,491</td><td style="width: 50%; padding: 5px;">Filed July 1, 2003</td></tr><tr><td colspan="2" style="padding: 5px;">First Named Inventor Vahid SAADAT</td></tr><tr><td style="padding: 5px;">Art Unit 3734</td><td style="padding: 5px;">Examiner Diane D. Yabut</td></tr></table>		Application Number 10/612,491	Filed July 1, 2003	First Named Inventor Vahid SAADAT		Art Unit 3734	Examiner Diane D. Yabut
Application Number 10/612,491	Filed July 1, 2003								
First Named Inventor Vahid SAADAT									
Art Unit 3734	Examiner Diane D. Yabut								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 20px;"><div style="width: 45%;"><p>I am the</p><div style="margin-bottom: 10px;"><input type="checkbox"/> applicant/inventor.</div><div style="margin-bottom: 10px;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</div><div style="margin-bottom: 10px;"><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,565</u></div><div><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</div></div><div style="width: 50%; text-align: center;"><div style="margin-bottom: 10px;"> Signature</div><div style="margin-bottom: 10px;"><u>Johney U. Han</u> Typed or printed name</div><div style="margin-bottom: 10px;"><u>(650) 242-4217</u> Telephone number</div><div><u>August 16, 2010</u> Date</div></div></div>									

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: August 16, 2010

Signature:  (Quyen Nguyen)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/612,491
Confirmation No.: 3557
Filing Date: July 1, 2003
Inventor(s): Vahid SAADAT et al.
Title: METHODS FOR REDUCTION OF A GASTRIC LUMEN
Examiner: Yabut, Diane D.
Group Art Unit: 3734

REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Final Office Action mailed February 16, 2010 ("the Office Action"), in the above-identified United States Patent Application. Filed herewith is a Notice of Appeal and a petition and fee for a three month extension of time. Accordingly, this response is timely filed. No fee is required for the Notice of Appeal because a fee was paid for a Notice of Appeal previously filed in this application. The Commissioner is authorized to charge any other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02112**.

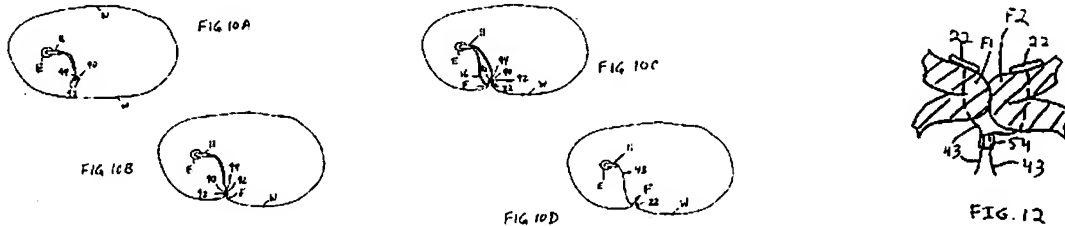
A pre-appeal brief review is requested for the reasons set forth below.

INTRODUCTION

The claims on appeal describe methods for delivering and deploying a tissue anchor into tissue of the gastrointestinal lumen of a patient for the purpose of, for example, reducing the cross-sectional area or volume of the lumen in order to promote weight loss. Exemplary embodiments of the method are set forth in Figures 10A-D and 12, which are reproduced below. Figures 10A-D show a delivery catheter 11 having a translatable needle 16 and a deployable stabilization device (jaw assembly 90). The jaw assembly 90 is used to grab and pull tissue from the tissue wall W to create a tissue fold F (see Fig. 10B). Creating the tissue fold F facilitates penetration of the tissue wall W by the needle 16 and subsequent delivery of

an anchor assembly 22. The jaw assembly 90 and needle 16 are then retracted into the delivery catheter 11 as the tissue fold F is maintained by applying tension to the suture 43.

The process is repeated to create



more tissue folds, which are approximated by applying tension to the sutures and then using a fastener 54 to secure the folds in the approximated position, as shown in Fig. 12.

ISSUES ON APPEAL

At issue are the following: (a) whether claims 1-3, 5-7, 9, 16, 26, and 32-40 should be rejected under 35 U.S.C. § 103(a) as being unpatentable over USP 6,736,828 to Adams et al. ("Adams") in view of USP 6,506,190 to Walshe ("Walshe") and USP 7,186,262 to Saadat ("Saadat"); (b) whether claims 4 and 27 should be rejected under 35 U.S.C. § 103(a) over the combinations of Adams, Walshe, and Saadat, in further view of US Pub. No. 2004/0194790 to Laufer et al. ("Laufer"), and in further view of USP 6,746,460 to Gannoe ("Gannoe").

ARGUMENT

I. Rejection of Claims 1-3, 5-7, 9, 16, 26, and 32-40 Under 35 U.S.C. § 103(a)

Claims 1-3, 5-7, 9, 16, 26, and 32-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams in view of Walshe and Saadat. In support of these rejections, the Office Action acknowledges (at pg. 3) that the Adams patent fails to teach "at least one of the anchors comprising a sleeve of braided material and an eyelet for attaching the anchor to a suture," as recited in the independent claims. The Office Action relies upon the Walshe patent for these features, and asserts:

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a braided material with an eyelet to the stent anchors of Adams et al., as taught by Walshe, in order to facilitate attachment with suture.

The Office Action further acknowledges that Adams fails to disclose "translation of a fastener over the suture whereby a tension force is created on the suture and the tissue fold is maintained." For these claim limitations, the Office Action relies upon the disclosure contained in the Saadat patent, and asserts:

It would have been obvious to one of ordinary skill in the art to modify Adams et al. by using a fastener and suture to the anchors of Adams et al., as taught by

Saadat, so that the tension is maintained and the fastener may be translated over the suture after the tissue has been approximated to adjust tension on the tissue wall.

For the following reasons, Appellant respectfully traverses these assertions.

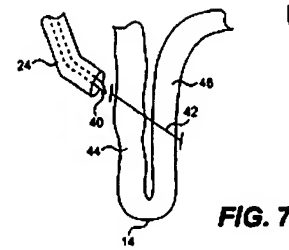
Three criteria must be met in order to establish a prima facie case of obviousness under 35 USC § 103(a) in view of a combination of references. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the references must teach or suggest all the claim limitations. Here, the proposed combinations of Adams, Walshe, and Saadat fail to satisfy at least the first two criteria.

Turning first to the proposed combination of the Walshe patent with the Adams patent, Adams discloses a fundoplication apparatus and method that includes ejecting a T-type fastener (42) out of a hypotube (40) and through the gastric and esophageal walls of a patient. Walshe, on the other hand, teaches a tissue anchor system that includes a tissue anchor (20) having a barb end (21) and a shaft (120), wherein the barb end resists removal of the anchor from tissue after the anchor has been inserted.

As to the first criterion for establishing a prima facie case of obviousness, there is no suggestion or motivation in either Adams or Walshe to combine or modify the teachings of the references in the manner proposed in the Office Action. The proposed rationale – that it would have been obvious to provide Walshe’s braided material with an eyelet to the Adams stent anchors “in order to facilitate attachment with suture” – is merely a conclusory statement and does not provide any sufficient reasoning as to why “attachment with suture” would have been desired by one of ordinary skill in the art considering the apparatus and method of Adams.

For example, Walshe’s stated purpose for providing and suturing the holes (61) of the button (62) to tissue is to prevent the button from migrating after deployment. (Walshe, col. 8, ll. 21-28). This makes sense given that the barb end of the Walshe tissue anchor is typically embedded in tissue and therefore susceptible to becoming dislodged or otherwise migrating. This is not the case with the Adams T-anchors, however, which are deployed through a tissue fold such that each of the ends of the anchor (42) extends over the tissue surface on opposite sides of the fold. (See, e.g., Adams Fig. 7, at right). As a result, Adams does not have the same concern about

migration of the anchor as does Walshe. Accordingly, the rationale stated in the Office Action for modifying



Adams per the teachings of Walshe is not supportable.

As to the second criterion, the proposed combination of Adams and Walshe does not show a reasonable expectation of success because the Walshe tissue retainer (27) / button (62) having holes (61) formed therein could not be readily incorporated into the Adams tissue anchors. The Adams fundoplication procedure is performed endoluminally using an endoscope or other similar device. (Adams, col. 4, ll. 16-25). Neither Adams nor Walshe describe any manner by which the holes (61) of the buttons (62) of the Walshe anchors – if somehow provided on the Adams anchors – could be sutured endoluminally to attach the buttons to the tissue. Given these structural and operational differences, there does not appear to be any reasonable expectation of success in combining the teachings of the two references. Certainly the Office Action does not describe how such a modification would be achieved.

Adding the Saadat patent to the combination of Adams and Walshe only compounds these deficiencies. Saadat relates to methods for thermally or mechanically treating tissue, particularly cardiac tissue, and describes translating a fastener 532 over a suture 506 to maintain tension in the suture. This is in contrast to the Adams apparatus, which includes various T-anchor embodiments having a fixed length, and the Walshe device describing neither of these constructions or modes of operation. As to the first two criteria discussed above for establishing a prima facie case of obviousness, once again there is no suggestion or motivation in either Adams or Saadat to combine or modify the devices or their methods of use. The rationale proposed in the Office Action – that Adams would have been modified to include Saadat's fastener and suture in order to adjust and maintain maintain tension in the suture – is again merely a conclusory statement and does not satisfy the standards for establishing a case of prima facie obviousness of the claims. Adams does not identify this as a desirable objective.

In addition, adding the Saadat fastener and suture onto the Adams device would significantly change its principle of operation. Adams describes a deployment device that

deploys T-anchors having a fixed distance between the opposed anchors. Providing a fastener that requires adjusting that distance would result in a significant departure from the operating principle of the Adams device, with no commensurate teaching as to how this might be done. Such a change would not have been obvious to a person skilled in the art. See, e.g., *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP § 2143.01.

For at least these reasons, none of Adams, Walshe, or Saadat provides any clear and particular motivation to combine the references in the manner proposed in the Office Action. Nor is there any reason to expect that such combinations would be successful. Appellant respectfully submits that the Office Action failed to satisfy at least the first and second criteria for establishing a prima facie case of obviousness, and that the rejections of claims 1-3, 5-7, 9, 16, 26, and 32-40 based thereon must be withdrawn.

II. Rejections of claims 4 and 27

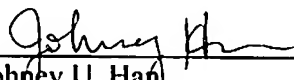
Neither the Laufer publication nor the Gannoe patent corrects the deficiencies of the combination of the Adams, Walshe, and Saadat patents discussed in Section I above. Accordingly, there can be no prima facie case of obviousness of claims 4 and 27 based upon the combinations of references set forth in the Office Action. For these reasons, the rejections of claims 4 and 27 cannot be supported, and must also be withdrawn.

CONCLUSION

In view of the foregoing, the Application is in condition for allowance. The rejections of the pending claims set forth in the Final Office Action should be withdrawn and the claims passed to issue.

Respectfully submitted,

Customer No. 40518
Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 242-4217
Fax: (650) 284-2180


Johnny U. Han
Registration No. 45,565

Charles C. Fowler
Registration No. 39,675